IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

VISTA HEALTHPLAN, INC., on behalf of itself and all others similarly situated, **Plaintiff,** **v.** **CEPHALON, INC., BARR LABORATORIES, INC., MYLAN LABORATORIES, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., RANBAXY LABORATORIES, LTD. and RANBAXY PHARMACEUTICALS, INC.,** **Defendants.**	**Civil Action No. _____** **JURY TRIAL DEMANDED** **CLASS ACTION COMPLAINT**

Plaintiff Vista Healthplan, Inc. ("Plaintiff"), on behalf of itself and all others similarly situated, sues defendants Cephalon, Inc. ("Cephalon"), Barr Laboratories, Inc. ("Barr"), Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. ("Teva"), Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy"), and Mylan Laboratories, Inc. ("Mylan") (collectively "Defendants"), and, based upon personal knowledge as to facts pertaining to themselves, and upon information and belief as to all other matters, alleges as follows:

NATURE OF THE ACTION

1. This is a civil antitrust action seeking treble damages arising out of Defendants' unlawful exclusion of generic competition from the market for modafinil, a drug marketed by Cephalon as a "wakefulness promoting agent," and indicated for the treatment of certain sleep disorders, including narcolepsy. Modafinil is sold by Cephalon under the brand name Provigil.

2. As detailed below, Cephalon engineered a conspiracy to restrain trade, and a scheme to monopolize the U.S. market for pharmaceutical products with modafinil as the active ingredient (the "modafinil market"), by substantially delaying the onset of generic competition for its top selling drug, Provigil. Among other aspects of its exclusionary scheme, Cephalon entered into agreements with its prospective generic competitors Teva, Barr, Mylan and Ranbaxy (collectively the "Generic Defendants"), whereby Cephalon agreed to pay the Generic Defendants a total of up to $136 million, as well as provide other compensation, in exchange for agreements by the Generic Defendants not to sell their generic versions of Provigil until October 2011 (or April 2012, under certain circumstances described below).

3. Generic versions of brand name drugs contain the same active ingredient, and are found by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generics and brand name drugs is their price – generics are typically at least 30% less expensive than their brand counterparts when there is a single generic competitor; this discount typically increases to 50-80% (or more) when there are multiple generic competitors on the market. As a result, generics constitute both: (a) an opportunity for drug purchasers and consumers to obtain enormous cost savings; and (b) a serious threat to the monopoly power and profits of the manufacturer of the brand name drug facing generic competition. Indeed, AB-rated generic versions of brand name drugs typically take 80% or more of the sales of a drug molecule from the brand name product within a year of generic entry.

4. Acutely aware of these economic realities of the pharmaceutical industry, Cephalon engineered a scheme whereby it would, *inter alia*: (a) make significant payments to the Generic Defendants in exchange for their agreements to refrain from selling their less expensive generic

versions of Provigil until either 2011 or 2012 (*i.e.*, for up to at least 6½ years); and (b) disguise these "exclusion payments" as payments for: (i) licenses and/or supply agreements regarding modafinil (regarding Teva, Barr and Ranbaxy); or (ii) product development agreements for unrelated products (regarding Mylan). Defendants intentionally concealed the true purpose and nature of these exclusion payments in an attempt to shield their exclusionary agreement from antitrust scrutiny.

5. Cephalon knew that its patent infringement claims against the Generic Defendants were weak, and thus, under applicable patent law, it could not use its patent to obtain a court order excluding the Generic Defendants from coming to market after Cephalon's Orphan Drug Exclusivity expired on December 24, 2005. That is why, in November 2005, prior to paying the Generic Defendants to stay off the market until at least 2011, Cephalon, in giving guidance to securities analysts regarding its forecasted sales and earnings for 2006, expressly stated that it expected generic competition for Provigil in 2006. After executing the exclusionary agreements with the Generic Defendants, however, Cephalon immediately and significantly increased its projected sales and earnings for 2006, because it knew that the agreements precluded competition from the Generic Defendants until at least 2011.

6. Absent the illegal agreements not to compete with the Generic Defendants, generic competition for sale of modafinil would have commenced in or about January 2006, and Plaintiff and other direct purchasers of modafinil would have been able to purchase modafinil at significantly lower prices than they were forced to pay because of Defendants' illegal acts to delay generic competition.

7. As a result of their illegal scheme, Defendants: (1) illegally maintained Cephalon's monopoly power in the market for modafinil in the United States; (2) fixed, raised, maintained,

and/or stabilized the price of modafinil at supra-competitive levels; and (3) overcharged Plaintiff and other direct purchasers of Provigil from Cephalon by millions of dollars by depriving them of the results of competition from cheaper generic versions of Provigil.

8. Defendants' "exclusion payment" agreements constitute horizontal market allocation agreements, which are *per se* violations of Section 1 of the Sherman Act. Defendants' conduct also constitutes a conspiracy to restrain trade, in violation of Section 1 of the Sherman Act.

9. Similarly, as alleged in more detail below, Defendants violated § 2 of the Sherman Act through their scheme to improperly maintain and extend Cephalon's monopoly power by foreclosing or delaying competition from lower-priced generic versions of Provigil.

10. Cephalon's monopoly power in the modafinil market was maintained through willful, exclusionary conduct, as distinguished from growth or development as a consequence of a legally obtained valid patent, other legally obtained market exclusivity, a superior product, business acumen or historic accident.

JURISDICTION AND VENUE

11. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. §§ 22 and 26. In addition, this Court has jurisdiction over the state law claims pursuant to 28 U.S.C. § 1332(d), as amended in 2005, and 28 U.S.C. § 1367.

12. Venue is proper in this District under 15 U.S.C. § 22, and under 28 U.S.C. §§ 1391(b) and (c), 28 U.S.C. § 1407, because: (1) Defendants transact business and are found within this District; and (2) a substantial portion of the affected trade and commerce described below has been carried out in this District.

THE PARTIES

13. Plaintiff Vista Healthplan Inc., a Florida corporation, is a health benefits company with its principal place of business in Hollywood, Florida. Vista provides comprehensive health benefits to its members through agreements with participating pharmacies. Vista pays some or all of the costs of prescription drugs dispensed, including Provigil, to its members.

14. Defendant Cephalon is a company incorporated under the laws of the State of Delaware, with its principal place of business at 41 Moores Road, Frazer, PA 19355. Cephalon develops, manufactures, and markets pharmaceuticals and related products in the United States. Cephalon's common stock is traded on the NASDAQ National Market System under the symbol CEPH.

15. Defendant Barr is a company incorporated under the laws of the State of New York, with its principal place of business at Two Quaker Road, Pomona, New York 10970. Barr principally develops, manufactures and markets generic versions of brand name drugs.

16. Defendant Mylan is a company incorporated under the laws of the Commonwealth of Pennsylvania, with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Mylan's subsidiary, Mylan Pharmaceuticals, Inc., is located at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Mylan principally develops, manufactures and markets generic versions of brand name drugs.

17. Teva Pharmaceutical Industries, Ltd. is an Israeli company. Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd., is a company incorporated under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454. Collectively, the corporations

identified in this paragraph are referred to herein as Teva. Teva principally develops, manufactures and markets generic versions of brand name drugs.

18. Ranbaxy Laboratories, Ltd. is a company operating under the laws of India. Ranbaxy Pharmaceuticals, Inc., a wholly-owned subsidiary of Ranbaxy Laboratories, Ltd., with its principal place of business located at 600 College Road East, Suite 2108, Princeton, New Jersey 08540. Collectively, the corporations identified in this paragraph are referred to herein as Ranbaxy. Ranbaxy principally develops, manufactures and markets generic versions of brand name drugs.

CLASS ACTION ALLEGATIONS

19. Plaintiff brings this action on behalf of itself and as a representative of a Class defined as follows:

> All persons or entities throughout the United States and its territories who purchased and/or paid for Provigil or generic versions of Provigil for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (the "Class") during the period from January 2006, through the date on which the anticompetitve effects of Defendants' conduct cease ("the Class Period"). For purposes of the Class definition, persons and entities "purchased" Provigil if they paid some or all of the purchase price.

Excluded from the Class are all Defendants, their officers, subsidiaries and affiliates; all government entities (except for government-funded employee benefit plans); and all persons or entities that purchased Provigil for purposes of resale, or directly from any of the Defendants or their affiliates.

20. Plaintiffs seek class certification pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure as to declaratory and equitable relief sought herein, and Rule 23(b)(3) as to the damages sought herein.

21. Although Plaintiff does not know the exact number of Class members, it believes it to be, at a minimum, in the tens of thousands. Thus, members of the Class are numerous and joinder is impracticable. The Class members are identifiable, *inter alia*, from information and records that are required by law to be maintained by pharmacies, drugstores, pharmaceutical benefits managers, and managed care organizations

22. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by Defendants, *i.e.*, they paid artificially inflated prices for Provigil and were deprived of the benefits of competition from cheaper generic versions of Provigil as a result of Defendants' wrongful conduct.

23. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

24. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

25. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

26. Questions of law and fact common to the Class include:

a. whether Defendants' agreements constitute illegal market allocation agreements;

b. whether Defendants maintained Cephalon's monopoly power by delaying generic entry;

c. whether direct proof of Defendants' monopoly power is available, and if available, whether it is sufficient to prove Defendants' monopoly power without the need to also define a relevant market;

d. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

e. whether the activities of Defendants as alleged herein have substantially affected interstate commerce; and

f. whether, and to what extent, Defendants' conduct caused antitrust injury, and if so, the appropriate measure of damages.

27. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

28. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

FACTUAL ALLEGATIONS

A. The Regulatory Structure Pursuant to Which Generic Substitutes for Brand Name Drugs Are Approved

29. Under the Federal Food, Drug, and Cosmetics Act (21 U.S.C. §§ 301-392), manufacturers who create a new, pioneer drug must obtain the approval of the FDA to sell the new

drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

30. In 1984, Congress amended the Food, Drug and Cosmetics Act with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

31. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").

32. The ANDA relies on the scientific findings of safety and effectiveness included by the brand name drug manufacturer in the original NDA. The ANDA filer must demonstrate to the FDA that the generic drug it proposes to market is bioequivalent to the brand name drug.

33. As a counter-balance to this abbreviated process for bio-equivalent generic drugs, Hatch-Waxman streamlined the process for a brand name manufacturer to enforce its patents against infringement by generic manufacturers, and provided that, under certain conditions (as detailed below), the FDA could not grant a generic manufacturer final approval to market or sell a generic version of the brand name drug for up to 30 months.

34. When the FDA approves a brand name manufacturer's NDA, the FDA publishes any compound patents which (according to the brand name manufacturer) claim the approved drug in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." 21 U.S.C. §355(j)(7)(A)(iii). In the case of method of use patents, the FDA lists in the Orange Book any patents which (according to the brand name manufacturer) claim

the approved drug for its approved method of use. In listing patents in the Orange Book, the FDA merely performs a ministerial act. The FDA does not check the facts supplied to it by the brand name manufacturer, but trusts that the manufacturer will be truthful. After the NDA is approved, the brand name manufacturer may list other new patents in the Orange Book as related to the NDA, if the brand name manufacturer similarly certifies, *inter alia*, that the new patents claim either the approved drug (for compound patents) or that the patents claim the approved drug for approved methods of use (for method-of-use patents).

35. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

36. If a generic manufacturer files only paragraph I, II, or III certifications, then it is able to take advantage of the expedited Hatch-Waxman approval process, and the FDA must act on the

application within 180 days of receipt, unless both the FDA and the applicant agree to extend the deadline. 21 U.S.C. § 355(j)(5)(A).

37. If a generic manufacturer files a Paragraph IV certification claiming that a patent listed in the Orange Book is invalid or will not be infringed, a brand name manufacturer has an opportunity to delay the final FDA approval of the ANDA and the sale of the competing generic drug on the market. When a generic drug manufacturer files a Paragraph IV certification with its ANDA, the generic manufacturer must promptly give notice of its certification to both the NDA-holder and the owner of the patent(s) at issue. If the NDA-holder initiates a patent infringement action against the ANDA filer within 45 days of receiving the Paragraph IV certification, then the FDA may not grant final approval to the ANDA until the earlier of either: (a) 30 months from the date the ANDA is filed; or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. §355(j)(5)(B)(iii). Thus, by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification regarding the listed patent, a brand name drug manufacturer may delay when the generic drug is finally approved by the FDA, and when generic competition to the brand name drug enters the market. During the pendency of the 30 month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would otherwise qualify for final approval but for the stay.

38. Because of the FDA rules alleged above, brand name manufacturers have an incentive to: (a) list patents in the Orange Book, even if such patents are not eligible for listing; and (b) then sue any generic competitor that files an ANDA with paragraph IV certifications, even if such competitor's product does not actually infringe the listed patent(s), in order to delay final FDA approval of an ANDA for up to 30 months. In addition, prior to a recent change in the Hatch-

Waxman regulations, brand companies could, and did, bring multiple infringement suits (based on multiple patents listed in the Orange Book) against a single ANDA, thereby obtaining independent 30-month stays associated with each suit. This practice was curtailed by a change in FDA regulations mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which, due to repeated abuses by brand manufacturers of the type described here, limited brand manufacturers to a single stay per ANDA. *See* 21 C.F.R. §§ 314.52, 314.95, 314.107(b)(3)(i)(A).

39. Hatch-Waxman also provides brand name manufacturers with other opportunities to obtain protection from generic competition. For example, if the FDA approves an NDA involving a new chemical entity (NCE), the brand manufacturer filing the NDA may obtain five years of exclusivity from the date of approval of the NDA. In addition, if an NDA drug treats a rare condition, FDA may, if appropriate, grant an additional two years of Orphan Drug exclusivity.

40. As detailed below, Cephalon sought and obtained both NCE and Orphan Drug exclusivity for Provigil. These exclusivities expired on December 24, 2003 and December 24, 2005, respectively.

B. Generic Versions of Brand Name Drugs are Significantly Less Expensive, and Take Significant Sales Directly From the Corresponding Brand Name Versions

41. Typically, generic versions of brand name drugs are priced significantly below the brand name versions. Because of the price differentials, and other institutional features of the pharmaceutical market, generic versions are rapidly and substantially substituted for their brand name counterparts. In every state, pharmacists are permitted (and, in most states, required) to substitute an AB-rated generic product for a brand name product unless the doctor has indicated that the prescription for the brand name product must be dispensed as written. As more generic

manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand name drug to the corresponding generic accelerates.

42. An AB rating is particularly significant to a generic manufacturer because, under the statutory regime enacted by both Congress (*i.e.*, Hatch-Waxman) and most state legislatures (which enacted Drug Product Selection, or DPS laws), pharmacists may substitute an AB-rated generic version of a drug for the brand name without seeking or obtaining permission from the prescribing doctor (unless the prescription is denominated "Dispense as Written," or DAW). Indeed, both Congress and the state legislatures have actively encouraged generic substitution because of their recognition that the economics of the pharmaceutical industry prevent generic manufacturers from simultaneously: (a) engaging in the type of heavy promotion or "detailing" typically done by brand name manufacturers; and (b) providing the enormous cost savings to purchasers and consumers generated by generic drugs.

43. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand name drug at a reduced price. However, until a generic manufacturer enters the market, there is no bioequivalent generic drug which competes with the brand name drug, and therefore, the brand name manufacturer can continue to charge supracompetitive prices profitably without losing all or a substantial portion of its brand name sales. Consequently, brand name drug manufacturers have a strong interest to use the tactics alleged above to delay the introduction of generic competition into the market.

C. Provigil

44. Provigil is a brand name drug manufactured by Cephalon. Provigil is marketed as a "wakefulness promoting agent" and is used in the treatment of certain sleep disorders, including narcolepsy and shift work sleep disorder. The active pharmaceutical ingredient in Provigil is modafinil.

45. Modafinil is a psychostimulant that enhances wakefulness and vigilance but its pharmacological profile, and thus its side effect and efficiency profile, is significantly different than drugs such as amphetamines and methylphenidate (Ritalin). These drugs are not AB-rated to Provigil, and are not reasonably interchangeable with modafinil.

46. The FDA approved Cephalon's NDA for Provigil on December 24, 1998, and Cephalon began selling Provigil shortly thereafter. Because modafinil constituted a new chemical entity (NCE), Cephalon received five years of NCE exclusivity. Provigil's NCE exclusivity expired on December 24, 2003.

47. Likewise, because Cephalon represented to the FDA that modafinil was a drug to treat a rare disorder (narcolepsy), Cephalon received Orphan Drug exclusivity, which expired on December 24, 2005.

48. In anticipation of the expiration of Provigil's NCE and/or Orphan Drug exclusivities, each of the Generic Defendants developed, and filed an ANDA seeking FDA approval for, AB-rated generic versions of Provigil. Each Generic Defendant filed its ANDA on December 24, 2002, the first day that ANDAs for generic version of Provigil could be filed under the NCE provisions of Hatch-Waxman. Thus, each of the Generic Defendants shared the 180 days of generic exclusivity

that is provided by Hatch-Waxman to the first generic challenger(s) to file ANDAs with Paragraph IV certifications.

49. Each of the Generic Defendants received tentative approval from the FDA for its generic version of Provigil prior to December 24, 2005, the date that Orphan Drug exclusivity for Provigil expired – Barr on January 7, 2004; Ranbaxy on February 18, 2004; Mylan on February 9, 2005; and Teva on December 16, 2005. "Tentative approval" means that an ANDA is deemed by FDA to be safe, effective and bioequivalent to its brand name counterpart, but the existence of some legal or regulatory barrier (such as Orphan Drug exclusivity) precludes the FDA from granting final approval to sell the generic product at issue.

50. As detailed further below, absent Defendants' wrongful and exclusionary conduct, each of the Generic Defendants would have obtained final FDA approval, and would have begun selling its generic version of Provigil – at prices significant below the price of brand name Provigil – on or shortly after the expiration of Provigil's Orphan Drug exclusivity on December 24, 2005.

D. Defendants' Wrongful Scheme to Delay Generic Competition

1. Cephalon's Provigil Patent and the Patent Litigation Against the Generic Defendants

51. The drug substance modafinil is an acetamide derivative. Both the compound modafinil and its neuropsychopharmacological profile have been known since at least the late 1980s.

52. On October 6, 1994, Cephalon scientists Peter Grebow, Vincent Corvari, and David Stong filed United States Application Serial No. 08/319,124 ("the '124 Application") titled "Acetamide Derivative Having Defined Particle Size" with the United States Patent & Trademark Office ("PTO"). Because the compound modafinil was prior art, the '124 Application could not

validly claim broadly the compound modafinil. Instead, the '124 Application narrowly claimed very specific formulations of modafinil, as well as certain uses of those narrow formulations.

53. In conjunction with filing the '124 Application, the named inventors (*i.e.*, Grebow, Corvari and Stong) assigned their interests to Cephalon and submitted declarations acknowledging their duty of candor (*i.e.*, the duty to disclose all material information) to the PTO and affirming that they were the true and properly named inventors for the '124 Application. This duty of candor extended to all named inventors, as well as to others such as patent attorneys and declarants substantively involved in the prosecution of the '124 Application. On April 8, 1997, the '124 Application issued as United States Patent No. 5,618,845 ("the '845 Patent").

54. On December 27, 1996, Cephalon filed new drug application no. 20-717 ("NDA No. 20-717") with the Food & Drug Administration ("FDA") seeking to market 100mg and 200mg strengths of modafinil under the brand name Provigil for the treatment of narcolepsy. On December 24, 1998, FDA approved NDA No. 20-717. Shortly thereafter, Cephalon began commercially marketing Provigil.

55. On or before April 1, 1999, Cephalon concluded that the '845 Patent was wholly or partly inoperative or invalid. Seeking to remedy perceived defects in the '845 Patent, Cephalon filed a reissue application ("the RE '166 Application"). The filing of the RE '166 Application triggered new duties of candor for those individuals substantively involved in the prosecution of the RE '166 Application. On January 15, 2002, the PTO issued reissue patent no. 37,516 ("the RE '516 Patent") and Cephalon surrendered the '845 Patent.

56. On or about February 12, 2003, Mylan notified Cephalon that it had filed ANDA No. 76-594 seeking to market generic versions of Provigil containing 100mg and 200mg of modafinil,

the active ingredient in Provigil. Mylan's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid claim of the RE '516 Patent.

57. On or about February 20, 2003, Barr notified Cephalon that it had filed ANDA No. 76-597 seeking to market generic versions of Provigil containing 100mg and 200mg of modafinil. Barr's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid and enforceable claim of the RE '516 Patent.

58. On or about February 25, 2003, Teva notified Cephalon that it had filed ANDA No. 76-596 seeking to market generic versions of Provigil containing 100mg and 200mg of modafinil. Teva's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid and enforceable claim of the RE '516 Patent.

59. On or about March 21, 2003, Ranbaxy notified Cephalon that it had filed ANDA No. 76-595 seeking to market generic versions of Provigil containing 100mg and 200mg of modafinil. Ranbaxy's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid claim of the RE '516 Patent.

60. On March 28, 2003, Cephalon filed suit in the United States District Court for the District of New Jersey alleging infringement of the RE '516 Patent by the Generic Defendants.

61. During discovery, as recited immediately below, the Generic Defendants uncovered facts supporting a host of defenses that cast serious doubt on: (1) the enforceability of the RE '516 Patent; (2) the validity of its claims; and (3) the strength of Cephalon's infringement theory.

62. For example, despite representations, declarations and/or suggestions to the contrary, the modafinil compositions and methods claimed in the '845 Patent and the RE '516 Patent (collectively the "Cephalon Patents") were manufactured and developed by scientists at Labortoire L. Lafon ("Lafon"), rather than scientists at Cephalon. Neither the named inventors of the '845 Patent nor the prosecuting attorneys informed the PTO about this material information during the prosecution of the '845 Patent. To the contrary, this material information was intentionally withheld from the PTO. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity to properly disclose these facts, but again intentionally declined to do so.

63. The named inventors and prosecuting attorneys similarly did not inform the PTO that Lafon sold and delivered modafinil tablets to Cephalon prior to the Cephalon Patents' critical date of October 6, 1993 under a Supply Agreement and a License Agreement executed in January of 1993. The modafinil tablets and modafinil active pharmaceutical ingredient ("API") sold and delivered to Cephalon prior to the critical date fall within some, if not all, of the composition claims recited in the Cephalon Patents. The sale and delivery of modafinil tablets and modafinil API under the Supply Agreement were highly material to patentability and were intentionally withheld by individuals substantively involved in the prosecution of the '845 Patent. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity to properly disclose these facts, but again intentionally declined to do so.

64. The named inventors and/or prosecuting attorneys for the Cephalon Patents intentionally misrepresented in the patent specification, and in Peter Grebow's September 26, 1995 declaration, that certain domestic and foreign clinical trials had followed the same protocol. In fact, the foreign clinical trial conducted by Lafon administered half of the daily dose of modafinil in each

of two daily doses whereas the domestic clinical trial conducted by Cephalon administered the entire daily dose in a single dose. During patent prosecution, Cephalon relied upon the existence of purported differences in adverse effects in the domestic and foreign trials in support of patentability, without telling the Examiner about the critical protocol change. The protocol change was material in part because it offered an explanation for the alleged adverse effects different than the explanation advanced by Cephalon in support of patentability. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity to properly disclose these facts, but again intentionally declined to do so.

65. The inventors and their attorneys misrepresented to the PTO in the Cephalon Patents specification that the adverse events observed in the domestic clinical trial at 800 mg doses were completely unexpected. Peter Grebow, a named inventor, further misled the PTO when he reiterated that contention in his September 26, 1995 declaration in support of patentability. In reality, Lafon informed Cephalon in February of 1993 that a single 600 mg dose of modafinil may cause adverse effects, a fact specifically known to Peter Grebow. Furthermore, the named inventors report in the specification that no clinically significant adverse events occurred in the foreign clinical trials conducted by Lafon. In fact, numerous serious adverse events were observed during those foreign clinical trials. Peter Grebow was aware of those instances of adverse events and even forwarded Lafon's "serious adverse event" information to a Canadian counterpart.

66. The named inventors and prosecuting attorneys at Cephalon also intentionally concealed from the PTO that the domestic clinical trial described in the Cephalon Patents, which used modafinil compositions covered by at least one of the composition claims, and which followed the method of administration falling within at least one of the method claims, occurred prior to both

the critical date and the alleged conception date. The subjects of the first United States clinical trial were members of the public, and they were under no obligation of confidentiality to Cephalon or the clinical investigators. The non-confidential, public clinical trial was material to patentability. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity to properly disclose these facts, but again intentionally declined to do so.

67. The named inventors and prosecuting attorneys also intentionally misrepresented to the PTO that the dog plasma level data discussed in the Cephalon Patents demonstrated that the claimed small particle modafinil compositions result in higher peak plasma levels than the large particle modafinil compositions of the prior art. Notwithstanding their representations to the PTO, the named inventors and prosecuting attorneys knew that the test results were not statistically significant. Indeed, the contrary was true. Cephalon's DM-93-014 report to the FDA includes representations directly contradictory to those made to the PTO. That report, completed at least as early as November 8, 1996 (*i.e.*, while the '845 Patent was still pending and before the RE '516 Patent was filed), concluded that there was no statistically significant difference in the peak plasma levels as a function of modafinil particle size. Cephalon agents with a duty of candor intentionally withheld the FDA report and the contradictory representations therein from the PTO during prosecution of the '845 Patent. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity to properly disclose these facts, but again intentionally declined to do so.

68. The named inventors and/or prosecuting attorneys also intentionally withheld the fact that Lafon had already considered the importance of maintaining particle size controls over modafinil drug product prior to Cephalon's alleged invention. Lafon provided Cephalon with particle size

information for all of the lots of modafinil API Lafon sold and delivered to Cephalon, including API Lot 003. The Cephalon Patents give the false impression that Cephalon was the first to measure particle size for modafinil and the first to recognize the importance of particle size. The named inventors and their attorneys also misrepresented to the PTO that one or more of the named inventors had discovered that the dissolution rate of modafinil increases with a decrease in particle size. In fact, Lafon scientists discovered the relationship between modafinil dissolution rate and particle size in 1989. Moreover, Lafon had communicated the relevant dissolution and particle size data to Cephalon in March of 1993. In addition, Peter Grebow represented to the PTO that there were no publications suggesting that the utility of modafinil could be improved by reducing its particle size when in fact he knew of a document published in September of 1993, more than one year prior to the filing date, which suggests that modafinil bioavailability differences may be caused by the particle size distribution. These misrepresentations and omissions were material to patentability. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity to properly disclose these facts, but again intentionally declined to do so.

69. In February 2005, the Generic Defendants filed amended answers alleging in detail the facts above supporting their inequitable conduct defenses and counterclaims. Many of these same facts supported a finding that some or all of the claims of the RE '516 Patent were invalid.

70. Based on the facts and circumstances alleged above, in August and September 2005, the Generic Defendants filed a series of motions seeking summary judgment that some or all of the claims of the RE '516 patent were invalid, as a matter of law. Those motions were fully briefed as of November 14, 2005.

71. Moreover, the Generic Defendants argued, in summary judgment motions filed with the patent court under Fed. R. Civ. P. 11, that their evidence of non-infringement was so clear and strong that the Generic Defendants were entitled to a finding, as a matter of law, that their generic products did not infringe the RE '516 Patent. (Most of the information relevant to these non-infringement claims is not publicly available.)

72. Starting in December 2005, Cephalon began settling its claims against the Generic Defendants. Each settlement culminated in a dismissal with prejudice, thereby allowing Cephalon to avoid a judicial resolution of the defenses the Generic Defendants had raised.

73. As a result of the facts and circumstances detailed above, each of the Defendants knew (or should have known) that, because Cephalon's patent claims were weak, and the Generic Defendants' patent defenses were strong, that absent settlements, it was highly likely that Cephalon would have lost the patent litigations involving Provigil on the merits.

2. The Prelude to the "Exclusion Payment" Agreements

74. Cephalon began selling modafinil, under the brand name Provigil in December 1998. Cephalon was the only company permitted to sell modafinil from December 1998 through December 2005 -- first, because it obtained five years of NCE exclusivity (which expired in December 2003), and then because it obtained two additional years of Orphan Drug exclusivity (which expired in December 2005).

75. Despite the fact that Cephalon received the two years of Orphan Drug exclusivity by representing to the FDA that Provigil was a niche drug used to treat a rare disorder (and thus supposedly had a limited potential market), sales of Provigil grew substantially, exceeding $420 million in 2004 and $500 million in 2005. The federal government is currently investigating whether

Cephalon improperly inflated its Provigil sales by allegedly illegally promoting or marketing Provigil for uses other than the limited/specific uses approved by the FDA - - *i.e.*, for "off label" uses.

76. Prior to December 2005, Cephalon recognized the likelihood that, despite the existence of its patent and its patent suits against the Generic Defendants, Cephalon would lose its modafinil monopoly at or about the time that its Orphan Drug exclusivity expired on December 24, 2005. There are several reasons why Cephalon knew before December 2005 that generic competition was imminent. First, three of the Generic Defendants had obtained tentative approval of their ANDAs for their generic versions of Provigil by January 2005. (The fourth Generic Defendant, Teva, received tentative approval on December 16, 2005.) As explained above, tentative approval means that: (a) the FDA has determined that the generic product is safe, effective and bioequivalent to its brand name counterpart; and (b) the only barrier to the grant of final approval to sell the generic product is the existence of some form of legal or regulatory exclusivity - - such as Orphan Drug exclusivity.

77. Since Cephalon knew that its Orphan Drug exclusivity was set to expire on December 24, 2005, it also knew that, if it did nothing: (a) the Generic Defendants were likely to obtain final approval of their ANDAs, and come to market with their generic versions of Provigil, on or shortly after December 24, 2005; and (b) Cephalon would quickly lose the vast majority of its Provigil sales, as purchasers would switch most of their modafinil purchases to the bioequivalent- -but substantially less expensive- -generic versions of Provigil.

78. Second, Cephalon knew that its RE '516 Patent would not preclude the Generic Defendants from coming to market on or shortly after December 24, 2005 because: (a) the 30 month stays, automatically obtained by Cephalon merely by filing their meritless patent suits against the

Generic Defendants (within 45 days of receipt of the generics' Paragraph IV Certifications), expired by no later than September 2005; (b) Cephalon's patent did not give it an automatic right to exclude its generic competitors, but rather a right to try to use its patent to obtain a court order excluding or enjoining generic competition; and (c) under controlling patent law, Cephalon would have been required to establish, *inter alia*, that it was likely to succeed on the merits of the underlying suit in order to obtain an injunction order to keep the Generic Defendants off the market after expiration of the 30 month stay. However, the weakness of Cephalon's patent claims, and the strength of the patent defenses raised by Generic Defendants in the underlying patent cases, precluded Cephalon from obtaining a court order enjoining generic competition. In fact, as detailed above, Cephalon could not have established a likelihood of success on the merits, because it was highly likely that, but for the settlements, Cephalon would have lost the patent cases on the merits.

79. Indeed, Cephalon management was so convinced that generic competition was imminent prior to December 2005 that they informed the investment community in November 2005 that Cephalon was projecting a substantial reduction of sales of Provigil in 2006, specifically because it expected generic competition to emerge in 2006.

80. Moreover, and significantly, Cephalon management also told securities analysts in November 2005 that Cephalon had reduced its promotional spending on Provigil in late 2005 because of its expectation that generic competition would commence promptly. It is common practice in the pharmaceutical industry for brand name manufacturers to reduce detailing for a brand name drug at or shortly before they expect generic competition. Such a reduction in promotion activity makes rational economic sense only if generic competition is expected in the very near

future, because the reduction in promotion, by itself, could lead to substantially reduced sales and profits for the brand name manufacturer.

81. Third, another tactic employed by Cephalon in light of expected generic competition was to develop, and seek FDA approval, for a new formulation of modafinil, which it called Nuvigil. Nuvigil purportedly has a longer-lasting effect than Provigil. Analysts, however, believed that Nuvigil did not constitute a significant or meaningful improvement over Provigil, but was simply a vehicle by which Cephalon could attempt to maintain its modafinil sales by attempting to convert demand for modafinil from Provigil, which faced imminent AB-rated generic competition to Nuvigil, which, upon information and belief, would not be AB-rated to -- and therefore not readily substitutable for - - the existing generic versions of Provigil.

82. From as early as the release of Cephalon's 2003 Annual Report, until the first settlements with the Generic Defendants were announced in December 2005, Cephalon publicly and repeatedly announced its intent to: (a) seek prompt FDA approval of Nuvigil; (b) begin selling Nuvigil upon such approval; and (c) convert the market demand for modafinil from Provigil to Nuvigil, which did not face imminent generic competition. Therefore, Cephalon's plans regarding Nuvigil were well known in the pharmaceutical industry - - and thus were known by the Generic Defendants -- when the Generic Defendants commenced settlement negotiations with Cephalon.

3. The Negotiation and Execution of Defendants' Market Allocation Agreements

83. Upon information and belief, in late 2005, Cephalon began negotiating settlements of the patent suits with some, if not all, of the Generic Defendants. Cephalon's primary goal in these negotiations was simple -- to delay generic competition for Provigil for as long as possible.

84. Because Cephalon's patent infringement claims against the Generic Defendants were weak, the existence of these claims would not deter the Generic Defendants from coming to market upon expiration of Cephalon's Orphan Drug exclusivity. The Generic Defendants would have to receive something of immediate and substantial value in order to induce them to forego their right to profit from the sale of their generic versions of Provigil after Cephalon's Orphan Drug exclusivity expired.

85. In order to protect and maintain its monopoly power in the modafinil market, it would have to induce all of the Generic Defendants to refrain from selling their generic versions of Provigil, because the entry of even a single generic product would quickly cause the majority of modafinil purchases to switch from Cephalon's branded Provigil to the substantially less expensive, but bioequivalent, generic version(s) of Provigil.

86. On December 9, 2005, Cephalon announced that it had reached an agreement to settle its patent litigation with Teva. The settlement agreement was not made available to the public. According to Cephalon's and Teva's press releases, however, under the agreement, Teva must keep its generic version of Provigil off the market until 2011 (or 2012, if Cephalon obtained a six-month pediatric exclusivity extension), unless another generic manufacturer enters the market prior to that time. Teva also received substantial (but undisclosed) cash payments.

87. The purpose and effect of the agreement was to delay generic competition to Provigil for 6 years or more, and thereby maintain and extend Cephalon's modafinil monopoly well past the date by which generic entry previously had been expected. In fact, following the settlements, Cephalon's Chief Executive Officer, Frank Baldino, Jr., candidly explained the rise in Cephalon's stock price following the announcements of the settlements as follows:

> "A lot of [Wall Street's enthusiasm for Cephalon's stock] is a result of the patent litigation getting resolved for Provigil. **We were able to get six more years of patent protection. That's $4 billion in sales that no one expected.**"

Philadelphia Business Journal, March 20, 2006.

88. Defendants claim the cash payments to Teva were in exchange for: (1) licenses to Teva's worldwide intellectual property "relating to the manufacture, development and formulation of modafinil"; and (2) "certain agreements with Teva relating to Teva's manufacture and supply of the active pharmaceutical ingredient modafinil." In fact, however, these payments were in exchange for Teva's agreement to keep its generic version of modafinil off the market until 2011 or 2012 (*i.e.*, for up to 6½ years).

89. The payments to Teva were, in fact, payments to exclude Teva's generic modafinil, based on several factors. First, prior to the settlement, Cephalon had been selling modafinil since February 1999 in the United States, and since 1998 in Europe, without a license under Teva's intellectual property. Thus, Cephalon had no need or use for a license from Teva -- other than to use such a license as a subterfuge to conceal the fact that it was paying Teva not to compete in the modafinil market for up to 6½ years.

90. Second, according to published reports, Cephalon also paid for a supply agreement from Teva for the active ingredient modafinil. Prior to its agreement with Teva, however, Cephalon had been able to obtain sufficient amounts of modafinil to meet market demand for almost seven years without a supply agreement, and did not suddenly need such an agreement in December 2005. Again, Teva's agreement to supply Cephalon with modafinil was simply a subterfuge to conceal the

fact that Cephalon was paying Teva not to compete with Cephalon's Provigil product for up to 6½ years.

91. Third, since Cephalon's patent claims were very weak, Teva's agreement to stay off the market until 2011 (or 2012) does not reflect a reasonable compromise of the patent suit based on the respective strength of Cephalon's claims and Teva's defenses. At the time of the settlement, there were approximately nine years remaining on Cephalon's patent, which is set to expire on October 6, 2014. Even though Teva was highly likely to win the patent case, it agreed to stay off the market for six of those nine remaining years. Thus, logic and economic rationality dictate that: (a) Teva must have received compensation for its agreement to stay off the market until 2011 (or 2012); and (b) the above-described payments to Teva were, in fact, for its agreement to keep its generic version of Provigil off the market, rather than for the licenses and supply agreements that Defendants claim were the compensation for these payments.

92. Fourth, as of the date of its settlement with Cephalon, Teva was well aware that its ability to market a generic version of Provigil in 2011 (or 2012) likely would be worth little (or nothing) because: (1) it knew of Cephalon's well-publicized efforts to convert all or most of the market demand for modafinil from Provigil to Nuvigil prior to the entry of generic versions of Provigil; and (2) Teva's generic product would not be AB-rated to -- and thus would not be substitutable by pharmacists for - - Nuvigil (since Nuvigil had a different dosage strength and/or formulation than Provigil). Thus, Teva knew that by the time it was permitted under its settlement agreement to sell its generic version of Provigil, its generic product was likely to generate little (if any) sales and profits, since it was likely that by that time, most (or all) of the demand for modafinil would have been converted to Nuvigil.

93. The agreement was intentionally structured in a manner that would buy Cephalon the time necessary to: (a) obtain FDA approval of its Nuvigil product; and (b) convert the market demand for modafinil from Provigil to Nuvigil. Indeed, prior to the agreement with Teva (and the agreements with the other Generic Defendants), Cephalon had publicly stated its plan to launch Nuvigil in early 2006, while continuing to market Provigil. After the agreements, however, Cephalon publicly stated that its intent was: (a) to delay marketing Nuvigil until 2010 - - a year before the Generic Defendants were permitted to sell generic versions of Provigil under the agreements; and (b) to stop promoting/selling Provigil at that point, and to convert market demand for modafinil from Provigil to Nuvigil prior to the market entry of generic Provigil.

94. The announcement of Cephalon's first settlement (with Teva) created expectations that Cephalon would settle with the other Generic Defendants. These expectations were reasonable because, as explained above, it made little economic sense for Cephalon to settle with less than all of the Generic Defendants, since any one of them would have toppled Cephalon's modafinil monopoly if they had come to market with an AB-rated generic equivalent to modifinil.

95. As expected, Cephalon in fact settled with the remaining Generic Defendants shortly after announcing its settlement with Teva.

96. Specifically, Cephalon settled with Ranbaxy on December 22, 2005; with Mylan on January 10, 2006; and with Barr on February 1, 2006. Like the Teva settlement, the Ranbaxy and Barr settlement agreements were not made publicly available. However, according to the parties' press releases and SEC filings, the Ranbaxy and Barr agreements, like the Teva agreement: (a) required the generic manufacturers to keep their generic versions of Provigil off the market until 2011 or 2012 (unless another generic enters the market before them); but (b) provided cash payments

to the generic manufacturers purportedly for licenses to the generics' worldwide intellectual property relating to modafinil and for supply/inventory purchase agreements with the generics.

97. Indeed, according to Cephalon's 2005 10-K, the payments to Teva, Ranbaxy and Barr will total up to $136 million.

98. And like the Teva agreement, the licenses and the supply agreements in the Ranbaxy and Barr agreements were merely subterfuges to conceal the fact that the payments to Ranbaxy and Barr were actually in exchange for their agreements to keep their generic versions of Provigil off the market for up to 6½ years.

99. While the press releases regarding the Mylan settlement did not disclose specific terms (other than Mylan's agreement to stay off the modafinil market until 2011 or 2012), upon information and belief, Cephalon similarly provided compensation to Mylan in exchange for its agreement not to compete. Indeed, not coincidentally, on the same day as Cephalon and Mylan executed their settlement agreement, the two companies executed two purported "product development collaboration agreements," under which Cephalon would make royalty payments to Mylan, purportedly on net sales of products unrelated to modafinil.

100. For the reasons detailed above, it would be economically irrational for Mylan to agree to keep its generic version of Provigil off the market for up to 6½ years unless it was receiving substantial compensation in exchange for its agreement not to compete.

101. Absent the Generic Defendants' illegal agreements not to compete with Cephalon for up to 6½ years, each and all of the Generic Defendants would have obtained final FDA approval to sell their generic versions of Provigil, and would have commenced selling their less expensive generic versions of Provigil, by no later than January 2006. Absent the illegal "exclusion payments"

they received from Cephalon, the Generic Defendants would have been motivated to begin selling its generic version of Provigil as soon as possible, in order to reap a (fair/substantial) return on the significant investment each had made in developing and seeking FDA approval for their generic versions of Provigil. Moreover, absent the exclusion payments they received from Cephalon, each of the Generic Defendants would have been motivated to come to market promptly because each knew that, if it did not come to market, the other Generic Defendants would likely do so, and capture the sales of generic Provigil that it otherwise would have obtained if it had come to market.

102. On or about March 28, 2006, Cephalon received a six-month pediatric exclusivity extension from the FDA. This extension, however, applies only to exclusivities which have not yet expired on the date that the extension is granted. Since Cephalon's Orphan Drug exclusivity for Provigil expired on December 24, 2005, Cephalon's receipt of a pediatric extension on March 28, 2006, over 90 days after the expiration of Cephalon's Orphan Drug exclusivity, would not have prevented the Generic Defendants from obtaining final FDA approval to sell their generic versions of Provigil prior to Cephalon's receipt of the pediatric extension.

E. Effect on Interstate Commerce

103. At all material times, Provigil, manufactured and sold by Defendant Cephalon, was shipped across state lines and sold to customers located outside its state of manufacture.

104. During the relevant time period, in connection with the purchase and sale of Provigil, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

105. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and

foreign telephone commerce. The activities of Defendants, as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

F. Monopoly Power

106. Through the anticompetitive conduct alleged herein, Cephalon was able to profitably charge supracompetitive prices for modafinil without losing substantial sales, and thus, by definition, maintained monopoly power with respect to modafinil sold in the United States. To the extent that Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is modafinil products – *i.e.*, Provigil (in all its forms and dosage strengths), and AB-rated bioequivalent version of Provigil. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which modafinil is prescribed. For the entire period relevant to this case, Cephalon has been able to profitably maintain the price of its branded modafinil product well above competitive levels without losing substantial sales.

107. The relevant geographic market is the United States and its territories.

108. Cephalon's market share in the relevant market is and was 100% at all times relevant to this complaint.

109. Defendants' actions are part of, and in furtherance of, the illegal restraint of trade and monopolization alleged herein, were authorized, ordered or done by Defendants' officers, agents, employees or representatives while actively engaged in the management of Defendants' affairs.

110. Defendants' illegal acts to prevent the introduction and/or dissemination into the U.S. marketplace of any generic version of Provigil resulted in Plaintiff and the Class paying more than they would have paid for modafinil, absent Defendants' illegal conduct.

G. Effects on Competition and Damages to Plaintiff and Class

111. Defendants' exclusionary conduct has delayed or prevented the sale of generic modafinil in the United States, and unlawfully enabled Defendants to sell Provigil at artificially inflated prices. But for Defendants' illegal conduct, generic competitors would have been able to successfully market generic versions of Provigil capsules by January 2006, and additional generic competitors would have entered the market thereafter.

112. If manufacturers of generic modafinil had entered the marketplace and effectively competed with Defendants earlier, as set forth above, Plaintiff and other members of the Class would have substituted lower-priced generic modafinil for the higher-priced brand name Provigil for some or all of their modafinil requirements, and/or would have received a lower price (and/or discounts) on some or all of their remaining Provigil purchases.

113. During the relevant period, Plaintiff and other members of the Class purchased substantial amounts of Provigil from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiff and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiff and the other Class members paid prices for modafinil that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic modafinil instead of expensive brand name Provigil; (2) Class members paid artificially inflated prices for generic modafinil and/or (3) the price of branded Provigil was artificially inflated by Defendants' illegal conduct. As a consequence, Plaintiff and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

COUNT I
(For Injunctive Relief Under Section 16 of the Clayton Act for Defendants' violation of Section 1 of the Sherman Act)

114. Plaintiff repeats and incorporates the preceding paragraphs as though set forth herein.

115. Beginning on or about December 9, 2005, Cephalon and each of the Generic Defendants engaged in continuing illegal contracts, combinations and conspiracies in restraint of trade, the purpose and effect of which was to: (a) allocate all sales of modafinil in the United States to Cephalon; (b) prevent the sale of generic version of modafinil in the United States, thereby protecting Provigil from any generic competition for up to 6½ years; and (c) fix the price at which purchasers would pay for Provigil at the higher, branded price.

116. By entering into these unlawful conspiracies, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. Defendants' agreements are horizontal market allocation and price-fixing agreements between actual or potential competitors, and thus are *per se* violations of Section 1. In the alternative, Defendants' agreements are unreasonable restraints of trade in violation of Section 1, when viewed under a "quick look" or "rule of reason" mode of analysis.

117. Plaintiff and the members of the Class have been injured in their business and property by reason of Defendants' unlawful contract, combination and conspiracy. Plaintiff and the Class members have paid more for their purchases of Provigil than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper generic for their purchases of the more expensive Provigil.

118. As a result of Cephalon's illegal conduct, Plaintiff and the Class paid more than they would have paid for modafinil, absent Cephalon's illegal conduct. But for Cephalon's illegal conduct,

competitors would have begun marketing generic versions of Provigil well before they actually did, and/or would have been able to market such versions more successfully.

119. If manufacturers of generic modafinil entered the market and competed with Cephalon in a full and timely fashion, Plaintiff and other Class members would have substituted lower-priced generic modafinil for the higher-priced brand name Provigil for some or all of their modafinil requirements, and/or would have received lower prices on some or all of their remaining Provigil purchases.

120. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Provigil. As a result of Cephalon's illegal conduct alleged herein, Plaintiff and the other Class members were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiff and all of the other Class members paid prices for modafinil that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) class members were deprived of the opportunity to purchase lower-priced generic modafinil instead of expensive brand name Provigil; (2) class members were forced to pay artificially inflated prices for generic modafinil and/or (3) the price of branded Provigil was artificially inflated by Defendants' illegal conduct.

121. Plaintiffs and the Class, pursuant to Rule 57 of the Federal Rules of Civil Procedure and 18 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct violates Section 1 of the Sherman Act.

122. Plaintiffs and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to remedy the anti-competitive market effects caused by the unlawful conduct of Defendants, and other relief so as

to assure that similar anti-competitive conduct does not occur in the future.

COUNT II
(For Injunctive Relief under Section 16 of the Clayton Act for Defendant's Violation of Section 2 of the Sherman Act – Against Cephalon Only)

123. Plaintiff repeats and incorporates the preceding paragraphs as though set forth herein.

124. Cephalon used various willful and exclusionary means as part of a scheme described herein to improperly maintain and extend their monopoly power in the modafinil market, as detailed above.

125. The goal, purpose and/or effect of Cephalon's scheme was to prevent, delay, and/or minimize the success of the entry of generic modafinil competitors which would have sold generic modafinil in the United States at prices significantly below Defendants' prices for Provigil, which would have effectively caused the average market price of modafinil to decline dramatically.

126. The goal, purpose and/or effect of Cephalon's scheme was also to maintain and extend Cephalon's monopoly power with respect to modafinil. Cephalon's illegal scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic version of Provigil enabled Cephalon to continue charging supra-competitive prices for modafinil without a substantial loss of sales.

127. As a result of Cephalon's illegal conduct, Plaintiff and the Class paid more than they would have paid for modafinil, absent Cephalon's illegal conduct. But for Cephalon's illegal conduct, competitors would have begun marketing generic versions of Provigil well before they actually did, and/or would have been able to market such versions more successfully.

128. If manufacturers of generic modafinil entered the market and competed with Cephalon in a full and timely fashion, Plaintiff and other Class members would have substituted

lower-priced generic modafinil for the higher-priced brand name Provigil for some or all of their modafinil requirements, and/or would have received lower prices on some or all of their remaining Provigil purchases.

129. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Provigil. As a result of Cephalon's illegal conduct alleged herein, Plaintiff and the other Class members were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiff and all of the other Class members paid prices for modafinil that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) class members were deprived of the opportunity to purchase lower-priced generic modafinil instead of expensive brand name Provigil; (2) class members were forced to pay artificially inflated prices for generic modafinil and/or (3) the price of branded Provigil was artificially inflated by Defendants' illegal conduct.

130. Cephalon's scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for modafinil in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

131. Plaintiffs and the Class, pursuant to Rule 57 of the Federal Rules of Civil Procedure and 18 U.S.C. § 2201(a), hereby seek a declaratory judgment that Cephalon's conduct violates Section 2 of the Sherman Act.

132. Plaintiffs and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to remedy the anti-competitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

COUNT III
(For Compensatory and Multiple Damages under the Antitrust and/or Consumer Protection Statutes of the Indirect Purchaser States)

133. Plaintiff repeats and realleges the preceding paragraphs as though set forth herein.

134. Defendants' conduct described herein constitutes an unlawful restraint of trade, as well as prohibited deceptive acts and practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Indirect Purchaser States, as follows:

(a) Arizona: Ariz. Rev. Stat. §§ 44-1401, *et seq.*;

(b) California: Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

(c) District of Columbia: D.C. Code §§ 28-4501, *et seq.*;

(d) Florida: Fla. Stat. Ann. §§ 501.201, *et seq.*;

(e) Iowa: Iowa Code §§ 553.1, *et seq.*;

(f) Kansas: Kan. Stat. Ann. §§ 50-101, *et seq.*;

(g) Louisiana: La. Rev. Stat. Ann. §§ 51:121, *et seq.*;

(h) Maine: Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*;

(i) Massachusetts: Mass. Gen. Laws ch. 93A, *et seq.*;

(j) Michigan: Mich, Comp. Laws §§ 445.771, *et seq.*;

(k) Minnesota: Minn. Stat. §§ 325D.49, *et seq.*;

(l) Mississippi: Miss. Code Ann. §§ 75-21-1, *et seq.*;

(m) Nebraska: Neb..Rev. Stat. §§ 59-801, *et seq.*;

(n) Nevada: Nev. Rev. Stat. §§ 598A, *et seq.*;

(o) New Mexico: N.M. Stat. Ann. §§ 57-1-1, *et seq.*;

(p) New York: N.Y. Gen. Bus. Law §§ 340, *et seq.*;

(q) North Carolina: N.C. Gen. Stat. §§ 75-1, *et seq.*;

(r) North Dakota: N.D. Cent. Code §§ 51-08.1-01, *et seq.*;

(s) South Dakota: S.D. Codified Laws §§ 37-1, *et seq.*;

(t) Tennes*See*: Tenn. Code Ann. §§ 47-25-101, *et seq.*;

(u) Vermont: Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*;

(v) West Virginia: W. Va. Code §§ 47-18-1, *et seq.*; and

(w) Wisconsin: Wis. Stat. §§ 133.01, *et seq.*

135. As a result of the conduct described above, Plaintiff and the Class have sustained and will continue to sustain substantial losses and damage to their businesses and property in the form of, *inter alia*, being deprived of the ability to purchase less expensive, generic versions of Provigil, and paying prices for Provigil products that were higher than they would have been but for Defendants' improper and unlawful actions. The full amount of such damage is presently unknown and will be determined after discovery and upon proof at trial.

136. Furthermore, the conduct complained of herein has "substantially affected" the people of Wisconsin and had impacts in Wisconsin, and the actions and transactions alleged herein have occurred "primarily and substantially" within Massachusetts, as those terms are understood under Wisconsin and Massachusetts law. To the extent that any notice needs to be sent pursuant to any of the statutes referenced in this Count, such notice will be sent as required by the Court.

137. Plaintiff and the Class seek damages, multiple damages, treble damages, and other damages as permitted by state law, for their injuries caused by these violations pursuant to these statutes.

COUNT IV
(For Restitution, Disgorgement and Constructive Trust for Unjust Enrichment by Defendants)

138. Plaintiff repeats and realleges the preceding paragraphs as though set forth herein.

139. As a result of their unlawful conduct described above, Defendants have been and will continue to be unjustly enriched. Cephalon has been unjustly enriched, to the detriment of Plaintiff and the Class, by the receipt of unlawfully inflated prices and illegal profits on their sale of Provigil. Separately, the Generic Defendants have been unjustly enriched, to the detriment of Plaintiff and the Class, by the receipt of any and all payments made to them by Cephalon to keep generic Provigil off the market. Defendants have benefitted from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of their ill-gotten gains, including, but not limited to, all of the payments made to the Generic Defendants by Cephalon and the gains resulting from the overpayments for Provigil made by Plaintiff and the Class.

140. Plaintiff and members of the Class are entitled to some or all of the total amount of Defendants' ill-gotten gains resulting from Defendants' unlawful, unjust and inequitable conduct. Plaintiff and the Class are entitled to restitution and/or the establishment of a constructive trust consisting of all ill-gotten gains from which Plaintiff and the Class members may make claims on a *pro rata* basis.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that the Court:

(a) Determine that this action may be maintained as a class action pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure; and declare Plaintiffs as Class representatives;

(b) Declare the conduct alleged herein to be in violation of Sections 1 and 2 of the

Sherman Act, of the statutes of the Indirect Purchaser States set forth above, and the common law of unjust enrichment;

(c) Award Plaintiffs and each member of the Class damages and, where applicable, treble, multiple, and other damages, including interest;

(d) Award Plaintiffs and each member of the Class the amounts by which Defendants have been unjustly enriched;

(e) Enjoin Defendants from continuing the illegal activities alleged herein;

(f) Award Plaintiffs and the Class their costs of suit, including reasonable attorneys' fees and expenses as provided by law; and

(g) Award the Class further relief as the Court deems just and necessary.

JURY TRIAL DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff demands a trial by jury of all of the claims asserted in this Complaint so triable.

Dated: May 1, 2006

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